Gente Clave

DESIGN OF A COST-EFFECTIVE SWIMMING PROSTHESIS FOR TRANSTIBIAL AMPUTEE PATIENTS

DISEÑO DE UNA PRÓTESIS DE NATACIÓN RENTABLE PARA PACIENTES DE AMPUTACIÓN TIBIAL

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Abstract

KEYWORDS: prosthesis, swim fin, stress analysis, transtibial amputee.

A swim fin prosthesis has been manufactured for a transtibial amputee patient by 3D printers using glycol-modified polyethylene terephthalate associated with a video recording analyzer that allows the measurement of the angles of the participant's residual limb. The data provided by the study indicate that the knee flexors present, according to Daniel's scale, the strength of 3.5, the knee extension (quadriceps-rectus femoris) a strength of 4, and the adductors (adductor medius) and abductors (gluteus medius, tensor fascia lata) a strength of 4. Mathematical modeling was performed to determine the critical loading conditions, considering some parameters that affect the mechanics of the transtibial amputee's kick, such as the angular velocity of the kick, drag force, and flipper geometry. Similarly, the mechanical strength of the prosthesis was evaluated by finite element analysis, and it was determined that given the angular velocity of the prosthesis, the maximum stress Von Miss 31.78MPa. In tests, the equipment operated at a pressure of 6.1 kPa.

Resumen

PALABRAS CLAVE: Próstesis, aleta de natación, análisis de esfuerzo, amputado tibial.

Se ha fabricado una prótesis de aleta de natación para un paciente con amputación transtibial mediante impresoras 3D utilizando tereftalato de polietileno modificado con glicol asociado a un analizador de grabación de vídeo que permite medir los ángulos del muñón del participante. Los datos aportados por el estudio indican que los flexores de rodilla presentan, según la escala de Daniel, una fuerza de 3,5, los extensores de rodilla (cuádriceps-recto femoral) una fuerza de 4, y los aductores (aductor medio) y abductores (glúteo medio, tensor de la fascia lata) una fuerza de 4. Se realizó un modelado matemático para determinar las condiciones críticas de carga, considerando algunos parámetros que afectan la mecánica de la patada del amputado transtibial, como la velocidad angular de la patada, la fuerza de arrastre y la geometría de la aleta. De igual forma se evaluó la resistencia mecánica de la prótesis mediante análisis de elementos finitos, y se determinó que dada la velocidad angular de la prótesis, el esfuerzo máximo de Von Miss 31.78MPa. En las pruebas, el equipo operó a una presión de 6,1 kPa.

INTRODUCTION

Amputation of one or more limbs creates a functional disability and can decrease a person's mobility level. Playing sports grants access to benefits that include improvements in health, social interaction, improved body image, and psychosocial well-being. Previous research has indicated prosthetic technology's value to the user's potential performance and emotional state. Ultimately, a specific activity such as swimming offers rehabilitation-based benefits and is one of the most common forms of cardiovascular for those with lower-limb amputations (Deans et al., 2012; Dyer & Deans, 2017; Jefferies et al., 2012; Le Clair, 2011). In swimming, essential factors, such as the lower extremities, mainly improve performance. Their primary action is to balance the body in the swim and thus help maintain an excellent hydrodynamic position (Royo, 2018). Swimming is known worldwide as the most comprehensive and physically demanding sport due to the wide variety of muscles used when swimming in each style (Royo, 2018). The amputation of limbs creates a disability and can reduce a person's mobility levels (Dyer & Deans, 2017). After amputation, a reduction in the size of the residual limb is created, the subcutaneous fat is reduced and dispersed, causing a decrease in muscle volume(Garcia Garrido et al., 2000).

According to the World Health Organization (WHO) world report on disability, it was evaluated that more than 1 billion people in the world have some disability (Organization, 2011). According to the census in Panama in 2010 (Rodríguez, 2010), persons with disabilities represented 2.9% of the total population. Six types of disability were recognized, with physical disability accounting for 30.1% of the population (Rodríguez, 2010). Most of these percentage live in rural areas, where it is difficult for them to get around or receive good medical care with the appropriate consistency required by a disability. Since these are rural areas, the inhabitants often resort to traditional medicine, losing interest in specialized care that provides them with resources and access to devices that improve their quality of life (Organization, 2011). Some alternatives may be upper or lower limb prostheses and wheelchairs. However, there are no references on the percentage of disabled people by type of amputation.

For an amputee, prostheses can be very expensive. A below-knee prosthesis costs approximately 6 thousand dollars in the market, and above-knee prostheses range between 9 thousand and 12 thousand dollars. These prostheses are made with acrylic resin, aluminum, and titanium, with about two months delivery time. In the Prosthesis and Orthosis Workshop of the Dr. Arnulfo Arias Madrid hospital complex, between 60 and 80 upper and lower limb prostheses were manufactured. However, swimming prostheses are not manufactured in Panama. For those with missing limbs, sport provides several benefits, including improved health, social interaction, and a good body image (Dyer & Deans, 2017).

Physical activities such as swimming offer rehabilitation-focused benefits and are among the most common ways people with lower-limb amputations can get cardiovascular exercise. People without limbs can swim easily without prostheses; however, swimming without prostheses can create imbalances, leading to injury (Garcia Garrido et al., 2000). Therefore, prosthetic technology will help strengthen residual limb muscles and promote functional symmetry (Dyer & Deans, 2017). Swimming considered a full-body exercise, strengthening muscles and allowing people to be independent in activities of daily living (walking, eating, dressing, grooming, and working, among others).

Addressing this challenge, the current study documents the design of an affordable swimming prosthesis for transtibial amputees that will allow them to increase physical activity, aid in muscle strengthening, increase cardiopulmonary capacity for use in aquatic activities (swimming), and strengthen muscles. (Goldstein et al., 2020; Schreiber & Gettens, 2014).

Theory

From the drag force (given by Equation 1 and 2), the area of the swim fin and the maximum stress to which the fin can be subjected can be determined:

$$F_{fin} = F_{leg} + F_{tibia/foot} \qquad \text{e.1}$$

$$\frac{1}{2}\rho_a C_a V_a^2 A_a = \frac{1}{2}\rho_t C_t V_t^2 A_t + \frac{1}{2}\rho_p C_p V_p^2 A_p \qquad \text{e.2}$$

Where ρ is the density of the fluid (water), V is the body's velocity, A is the area of the body, and C is the coefficient of friction which depends on the body's geometry. The subscript a, t, and p refer to the fin, leg, tibia, and foot area (Alan Valencia, 2010).

Since the linear velocity is related to the angular velocity, it is possible to write equation two as follows equation 2 to the following:

$$\frac{1}{2}\rho_a C_a (\omega_a r_a)^2 A_a = \frac{1}{2}\rho_t C_t (\omega_t r_t)^2 A_t + \frac{1}{2}\rho_p C_p \left(\omega_p r_p\right)^2 A_p$$

e.3

Given that $\omega_a = \omega_t = \omega_p$ are equal, and the density of the medium where each part is immersed in the same, Equation 3 can be readjusted by clearing for the area of a swim fin that generates the same thrust as the amputated limb:

$$A_a = \frac{C_t r_t^2 A_t + C_p r_p^2 A_p}{C_a r_a^2} \qquad \text{e.4}$$

Once the area has been calculated, to know the forces to which the fin would be subjected in the water while swimming, the drag force must be determined from the relative velocity of the fluid concerning the body (V), the mechanics of the kick, and the angular velocity with which the kick is performed (ω). The drag force on the fin is used to determine the pressure on the fin. The relationship between force and pressure is as follows:

$$F_a = \frac{1}{2}\rho_a C_a r_a^2 \omega_a^2 A_a \qquad \text{e.5}$$

$$P_a = \frac{F_a}{\mathrm{A}_a} \qquad \text{e.6}$$

If we approximate the fin area as rectangular, given Ca=1.875, r = 0.85cm, ω=3 rad/sec, and an A=0.02m2, the total pressure on the fin is 6.1 KPa.

Materials and Methods

Materials

A ROBO C2 3D printer with prototyping speed of 16mm3/s, travel speed of 250mm/s, and a printing range of 300 to 20 microns with the auto-leveling system; clog-free poly-lactic acid filament (MW 128-152 KDa) with a diameter of 1.75mm and a melting temperature of 190-200°C was used; a submersible Go Pro Hero 6 camera to evaluate the mechanics of the participant's kick in the water and Kinovea software for video analysis; a laboratory for Biomechanics gait analysis with optoelectronic cameras and surface EMG integration was also employed to analyze the mechanics of the participant's kick in the air and force. Finally, Autodesk Fusion 360 (2019) software was used for prototype design and finite element análisis.

Method

The research design is quantitative. And the type of study is cross-sectional. The population is people with transtibial amputation in Panama City. The sample is composed of volunteers with transtibial amputation residing in Panama City. The tests were performed as a controlled reversal: the participant was exposed to 2 different prosthesis conditions: a fixed prosthesis using air as a continuous phase and the same prosthesis in water (swimming pool test). Each trial was recorded for subsequent analysis of kick mechanics. The case study participant was recruited to participate from the local amputee population. Inclusion criteria for enrollment included 18 years or older, transtibial amputation with a minimum of 10 years post-amputation, and current prosthesis use. Exclusion criteria had chronic residual limb skin breakdown or secondary health problems prohibiting participation in study activities. Human subject approval was granted through a medical and physiotherapeutic evaluation by the Physical Activity and Sport Sciences Institute of the UDELAS. The engineer and the therapist evaluated the candidates independently. Informed consent was obtained from all subjects.

The protocol used for clinical evaluation consisted of an analysis of goniometry at the level of joint angles (detailed physical examination). Next, the functional deficit of joint mobility in limbs and spine was determined. Results were compared with the tables of average values for individuals of the same age and sex (Norkin, 2016; Preedy, 2012)

Muscle strength was determined based on the six-level scale proposed by Worthingham et al. (Worthingham, 2014) where:

- Grade 0: No muscle response.
- Grade 1: The muscle performs a noticeable contraction, although no movement is evident.
- Grade 2: The muscle performs all the joint movement once it is released from the effect of gravity.
- Grade 3: The muscle performs the entire movement against the action of gravity but without suggesting any resistance.
- Grade 4: The movement is possible in its full range, against the action of gravity and suggesting moderate manual resistance.
- Grade 5: The muscle supports maximum manual resistance.

Using the video player for sports analysis (Kinovea), it was possible to characterize the movement by obtaining times, angles, and, therefore, trajectory. From there, the stress on the fin could be calculated. Based on the observations, the prosthesis had several changes to ensure that the mechanics of the kick were not affected.

Fusion 360 software is used to recreate the material's performance under static loads for computational analysis. The loads are placed on the fin due to the water resistance from the video analysis. The maximum stress on the prosthesis and the maximum deflection is analyzed. The von Misses stresses are also determined to estimate the design and material's failure conditions.

Anthropometry

Different anthropometric measurements were taken to characterize the area where the prosthesis would be placed. Table 1 summarizes these values.

Table 1

Anthropometric Measurements

Section	Measurement
Measurement (in cm) of the thickness (circumference) of the calf.	32
Measurement (in cm) of the thickness (circumference) underneath the calf.	31.7
Length (in cm) of the leg, from the knee to the tip of the big toe.	57
Length (in cm) from the start of your legs to the tip of your big toe.	101

Prosthesis specifications

The prosthesis weight should be equal to or less than the contralateral (healthy) limb; the limit imposed was 1 kg since this is the weight of the patient's foot. The Braun and Fisher equation and table were used to calculate the foot's weight.

The anthropometric measurements in Table 1 were used; the clinical examination indicated that it should be similar to the contralateral limb. The prototype is 0.55 m long and 0.037 m wide. The general design considerations for the prosthesis are summarized in Table 2.

Table 2

Requirements summary table

Specification	Description	Measurement
Feasible manufacturing	Manufacture with affordable PLA raw material.	> 80% of its construction is made with inexpensive raw materials.
Low cost	Allow displacement in water.	Verify by the survey.
Flexibility and size	Be comfortable in the die and be flexible and withstand cyclic stresses.	Fixed
Easy to assemble	Avoid air accumulation in the coupling socket.	It has direct pyramidal coupling to the stump.
Weight and buoyancy	Lower density but close to that of water and lightweight.	

Results

Physiology

Knee flexors showed a strength of 3.5, knee extension (quadriceps-rectus femoris) at 4, adductors (adductor medius), and abductors (gluteus medius, tensor fascia lata) have a strength of 4 on the Daniel scale.

Goniometry at the level of joint angles (detailed physical examination) is shown in Figure 1. The functional deficit of joint mobility of the limbs was determined. The results were compared with tables of average values with amplitude values of individuals of the same age and sex. The reliability and validity of the goniometric measurements in measuring the joints of the upper and lower limbs are considered good to excellent.

Video analysis and validation

Once the relevant tests were performed, the participant's kicking dynamics were verified. The kick cycle is recorded in Figure 2. The observations are as follows:

- The evidence shows the beginning of the right leg's downward movement followed by the left leg's upward movement.
- The downward movement begins with the hip's flexion, followed by the knee extension.

- Rapid and robust knee extension until the knee is fully straightened. The last part of the downward movement is a downward thrust with the foot's instep.

The dynamics of the participant's kick were analyzed using Kinovea. Figure 3 shows the angular velocity from the geometric center of the fin to the horizontal. The average angular velocity was 3 rad s-1. A Savitzky Golay approximation was used for the original data.

Finite Element Stress Analysis

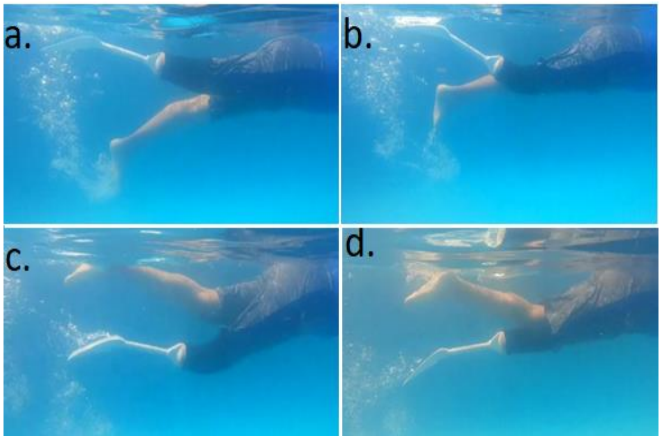
The design performance under different loads at critical conditions was simulated using Fusion 360. Figure 4 shows the location of the maximum stress (31.78 KPa). Note that for that pressure in the fin, the highest stress is in the part that joins the trunnion. The maximum deflection was 38.01mm and validated the performance of the proposed design with the assigned materials because the resulting maximum von Mises stress is less than the material's tensile strength, 31.78 MPa < 300MPa.

Figure 1

Detailed physical examination and joint angles

Figure 2

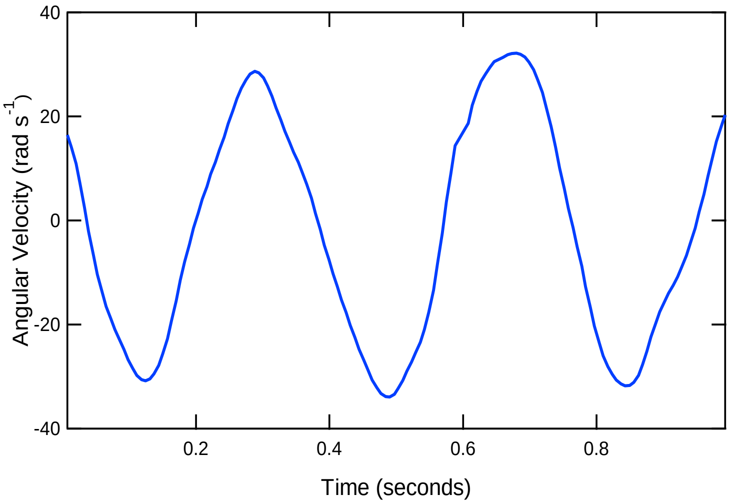
Dynamics of the fin kick



Note: a. beginning of right leg extension b. continuation of the downward movement of the right leg. End of the upward movement of the left leg. c. continuation of the downward movement of the right leg. End of the upward movement of the left leg d. rapid and strong extension of the knee until it is fully straightened. The last part of the downward movement is a downward push with the foot's instep.

Figure 3

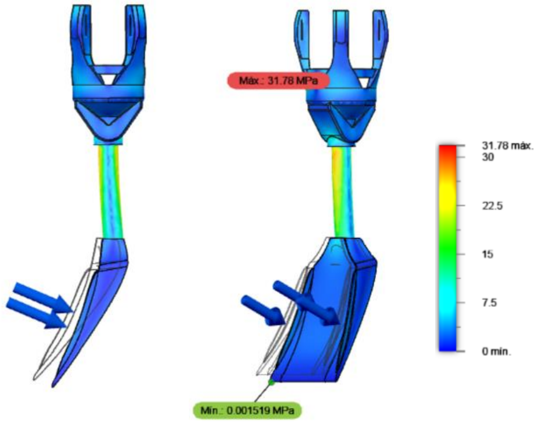
Angular velocity



Note: Angular velocity of the participant using the designed prosthesis. The dynamics of the kick are cyclic and low power.

Figure 4

Maximum stresses in the swim fin prosthesis



Note: The point of highest stress is where the fin begins (marked in yellow).

Discussion

Lower limb amputees encounter barriers to participation in physical activity, which include: difficulty in arranging transportation, inaccessible fitness facilities, social attitudes, climate, general physical environment, and income. These limitations play a role in preventing lower limb amputees from participating in swimming, physical activity that is likely to be recommended for this population. Currently, widely available swimming prostheses are difficult or impossible to use to walk on land or to transition between land and water. For those with missing limbs, sport provides several benefits, including improved health, social interaction, and good body image (Dyer & Deans, 2017).

Swimming activity offers rehabilitation-focused benefits and is one of the most common ways people with lower-limb amputations can get cardiovascular exercise. People without limbs can swim easily without prostheses; however, swimming without prostheses can create imbalances, leading to injury. Therefore, prosthetic technology can help strengthen residual limb muscles and promote functional symmetry (Dyer & Deans, 2017). Swimming is considered a comprehensive body exercise, strengthening muscles, and allowing people to be independent in the activities of daily living (walking, eating, dressing, grooming, working). The current study answers the disabled people's right to a healthy lifestyle.

Conclusion

The prosthesis works. Furthermore, it was designed to grant the participant a comfortable solution to access a healthy lifestyle based on a clinical evaluation. Further analysis of the hydrodynamic profile of the prosthesis given different flow conditions is required to evaluate its effectiveness and potential for use in competitions.

Author's Contributions

JM, MR, and MC wrote the first draft, including the conceptualization, data curation, formal analysis, investigation, methodology, project administration, investigation, resources, supervising, validation, and visualization. They contributed equally. CN, and GA worked on the clinical analysis. ST, DR, EI, and LE evaluated and analyzed the data. All authors read and approved the final manuscript.

Conflict of Interest

The authors declare that they have no conflicts of interest. The sponsors had no role in the design of the study, in the collection, analysis, or interpretation of data, in the writing of the manuscript, or in the decision to publish the results.

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